DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

JEW 5/11/00

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VIA FEDERAL EXPRESS

WARNING LETTER

FLA-00-52

May 5, 2000

George C. Kalemeris, Medical Director
Lee Memorial Hospital Blood Bank
2776 Cleveland Avenue
Ft. Myers, Florida 33901

Dear Dr. Kalemeris:

During an inspection of your unlicensed blood bank and laboratory on March 27-29, 2000, our investigator, Joan S. Norton, documented serious violations of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act), and the Current Good Manufacturing Practice (CGMP) regulations for blood and blood components [Title 21, Code of Federal Regulations, Part 606 (21 CFR 606)].

The inspection revealed that you have failed to adequately determine the suitability of persons to serve as whole blood donors. Donor suitability records are incomplete and fail to contain enough information to determine if donors are qualified for donation. At least twenty-four donors were accepted for donation with incomplete information documented in their donor history records. These records contain unanswered questions and/or questions answered in the positive with no documentation of further follow up or investigation to obtain answers or to clarify positive answers.

You have also failed to establish written procedures for all operations being performed by your blood bank. No written procedures are established for registering donors electronically, registering donors manually on your mobile unit, maintaining your donor base and searching for duplicate and/or unsuitable donors on a set schedule, review of donor suitability records to assure completeness prior to release of blood products for transfusion or your HCV lookback process.

In addition, viral marker test results are not being reviewed by a second person prior to release of blood products for transfusion, quality control records for viral marker testing were not reviewed by a supervisor from May 1999 through February 2000 and blood collection scales on your mobile unit are not being calibrated properly or taken out of service in accordance with your written procedure.

The above violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure that all blood and blood components produced and issued by your blood bank are in compliance with the Act and the CGMP regulations. You should take prompt action to correct these violations. Your failure to correct these violations may result in further regulatory action being taken by FDA without further notice. Such action includes seizure and/or injunction.

We request that you notify this office in writing, within fifteen (15) working days of receipt of this letter, of specific steps you have taken to correct these violations, including examples of any documentation showing that corrections have been achieved. If you cannot complete corrections within 15 working days, state the reason for the delay and the time period within which corrections will be completed.

Your reply should be directed to Jimmy E. Walthall, Compliance Officer, U.S. Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, telephone (407) 475-4731.

Sincerely,

Edward R. Atkins

Edward R. Atkins
Acting Director
Florida District